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I, JULIE BILLINGSLEY, TEAM LEADER EXAMINATION SUPPORT AND SALES hereby certify that annexed is a true copy of the Provisional specification in connection with Application No. PS 3225 for a patent by COCHLEAR LIMITED as filed on 28 June 2002.

WITNESS my hand this
Eleventh day of July 2003

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AUSTRALIA

Patents Act 1990

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PROVISIONAL SPECIFICATION

Invention Title:

A fibre optic stylet for an electrode array

The invention is described in the following statement:

Field of the Invention

The present invention relates to an implantable device and, in particular, to an implantable cochlear electrode assembly.

Background of the Invention

Hearing loss, which may be due to many different causes, is generally of two types, conductive and sensorineural. Of these types, conductive hearing loss occurs where the normal mechanical pathways for sound to reach the hair cells in the cochlea are impeded, for example, by damage to the ossicles. Conductive hearing loss may often be helped by use of conventional hearing aid systems, which amplify sound so that acoustic information does reach the cochlea and the hair cells.

In many people who are profoundly deaf, however, the reason for deafness is sensorineural hearing loss. This type of hearing loss is due to the absence of, or destruction of, the hair cells in the cochlea which transduce acoustic signals into nerve impulses. These people are thus unable to derive suitable benefit from conventional hearing aid systems, because there is damage to or absence of the mechanism for nerve impulses to be generated from sound in the normal manner.

It is for this purpose that cochlear implant systems have been developed. Such systems bypass the hair cells in the cochlea and directly deliver electrical stimulation to the auditory nerve fibres, thereby allowing the brain to perceive a hearing sensation resembling the natural hearing sensation normally delivered to the auditory nerve. US Patent 4532930, the contents of which are incorporated herein by reference, provides a description of one type of traditional cochlear implant system.

Cochlear implant systems have typically consisted of two key components, namely an external component commonly referred to as a processor unit, and an implanted internal component commonly referred to as a receiver/stimulator unit. Traditionally, both of these components have cooperated together to provide the sound sensation to an implantee.

The external component has traditionally consisted of a microphone for detecting sounds, such as speech and environmental sounds, a speech processor that converts the detected sounds and particularly speech into a coded signal, a power source such as a battery, and an external antenna transmitter coil.

The coded signal output by the speech processor is transmitted transcutaneously to the implanted receiver/stimulator unit situated within a recess of the temporal bone of the implantee. This transcutaneous transmission occurs through use of an inductive coupling provided between the external antenna transmitter coil which is positioned to communicate with an implanted antenna receiver coil provided with the receiver/stimulator unit. This communication serves two essential purposes, firstly to transcutaneously transmit the coded sound signal and secondly to provide power to the implanted receiver/stimulator unit. Conventionally, this link has been in the form of a radio frequency (RF) link, but other such links have been proposed and implemented with varying degrees of success.

The implanted receiver/stimulator unit typically included the antenna receiver coil that receives the coded signal and power from the external processor component, and a stimulator that processes the coded signal and outputs a stimulation signal to an intracochlea electrode assembly which applies the electrical stimulation directly to the auditory nerve producing a hearing sensation corresponding to the original detected sound.

It is known in the art that the cochlea is tonotopically mapped. In other words, the cochlea can be partitioned into regions, with each region being responsive to signals in a particular frequency range. This property of the cochlea is exploited by providing the electrode assembly with an array of electrodes, each electrode being arranged and constructed to deliver a cochlea-stimulating signal within a preselected frequency range to the appropriate cochlea region. The electrical currents and electric fields from each electrode stimulate the cilia disposed on the modiolus of the cochlea. Several electrodes may be active simultaneously.

It has been found that in order for these electrodes to be effective, the magnitude of the currents flowing from these electrodes and the intensity of the corresponding electric fields, are a function of the distance between the electrodes and the modiolus. If this distance is relatively great, the threshold current magnitude must be larger than if the distance is relatively small. Moreover, the current from each electrode may flow in all directions, and the electrical fields corresponding to adjacent electrodes may overlap, thereby causing cross-electrode interference. In order to reduce the threshold stimulation amplitude and to eliminate cross-electrode interference, it is advisable to keep the distance between the electrode array and the modiolus as small as possible. This is best accomplished by providing the electrode array in the shape which generally follows the shape of the modiolus. This also ensures that the delivery of the electrical stimulation to the auditory nerve is most effective as the electrode contacts are as close to the auditory nerves that are particularly responsive to selected pitches of sound waves.

In order to achieve this electrode array position close to the inside wall of the cochlea, the electrode needs to be designed in such a way that it assumes this position upon or immediately following insertion into the cochlea. This is a challenge as the array needs to be shaped such that it assumes a curved shape to conform with the shape of the modiolus and must also be shaped such that the insertion process causes minimal trauma to the sensitive structures of the cochlea. In this regard, it has been found desirable for the electrode array be generally straight during the insertion procedure.

One difficulty that can be faced by surgeons attempting to implant an electrode array is a cochlear having a scala tympani duct that is at least partially blocked or ossified. The present invention is directed to an electrode assembly adapted to overcome some of the difficulties of placing electrode arrays in such ducts.

Any discussion of documents, acts, materials, devices, articles or the like which has been included in the present specification is solely for the purpose of providing a context for the present invention. It is not to be taken as an admission that any or all of these matters form part of the prior art base or were

common general knowledge in the field relevant to the present invention as it existed before the priority date of each claim of this application.

Summary of the Invention

Throughout this specification the word "comprise", or variations such as "comprises" or "comprising", will be understood to imply the inclusion of a stated element, integer or step, or group of elements, integers or steps, but not the exclusion of any other element, integer or step, or group of elements, integers or steps.

According to a first aspect, the present invention is an implantable tissue-stimulating device comprising:

an elongate member having a plurality of electrodes mounted thereon and having a first configuration selected to allow said member to be inserted into an implantee's body, and at least a second configuration wherein said elongate member is adapted to apply a preselected tissue stimulation with the electrodes, said elongate member being made of a resiliently flexible first material; and

a stiffening element removably positionable within said member that biases said elongate member into said first configuration;

wherein said stiffening element comprises one or more optic fibres.

In a preferred embodiment of this aspect, the second configuration of the elongate member is curved. More preferably, the elongate member adopts a spiral configuration when in the second configuration.

According to a second aspect, the present invention is a cochlear implant electrode assembly device comprising:

an elongate electrode carrier member having a plurality of electrodes mounted thereon and having a first configuration selected to allow said member to be inserted into an implantee's cochlea, and at least a second configuration wherein said elongate member is curved to match a surface of said cochlea, said elongate member being made of a resiliently flexible first material; and

a stiffening element removably positionable within said member that biases said elongate member into said first configuration;

wherein said stiffening element comprises one or more optic fibres.

In a further embodiment, the elongate member can have a resiliently flexible tip member extending forwardly from the first end of the body of the elongate member. The tip member is preferably light permeable, and more preferably at least substantially transparent. In one embodiment, the tip member can be hemispherical in form. The diameter preferably gradually decreases to form a rounded end. The tip member preferably has a diameter of about 140μm.

The tip member preferably acts as a lens and allows visualisation of a region at least adjacent the tip member of the elongate member. In one embodiment, the tip member acts as a planar convex lens, however, other lens types can be formed.

According to a still further aspect, the present invention is a cochlear implant electrode assembly device comprising an elongate electrode carrier member having a proximal end, a distal end, and a plurality of electrodes mounted thereon between said proximal and distal ends, the carrier member having a first configuration selected to allow said member to be inserted into an implantee's cochlea, and at least a second configuration wherein said elongate member is curved to match a surface of said cochlea, said elongate member being made of a resiliently flexible first material and having a lumen formed therein extending from or adjacent the proximal end to or adjacent the distal end and adapted to receive a stiffening element removably positionable within said member that biases said elongate member into said first configuration, wherein said distal end of said carrier member comprises a transparent tip member.

In this aspect, the assembly device is preferably pre-packaged with a stiffening element positioned within the lumen of the member. The stiffening element is preferably a stylet comprising one or more optic fibres.

In the above aspects, the tip member preferably acts as a lens and allows illumination and/or visualisation of a region at least adjacent the tip member of the elongate member.

In one embodiment, the tip member is formed from a transparent silicone compound. The tip member can have a stiffness that is relatively less stiff than said stiffening element. The tip member can further be formed of a material that is substantially the same or the same stiffness as the body of the elongate member. In another embodiment, the tip member can be formed of a material that is relatively less stiff than at least a portion of the elongate member. In a further embodiment, the tip member can be formed of a material that undergoes a change in stiffness, preferably a decrease in stiffness, on insertion into the body, such as the cochlea.

In a further embodiment, the stiffness of the tip member can vary along at least a portion of its length from its distal end to its proximal end. In one embodiment, the stiffness of the tip member can vary over the entire length of the tip member or only a portion thereof. The stiffness can increase from the distal end to the proximal end. In one embodiment, the stiffness of the tip member over said portion or its length can increase gradually from its distal end towards to the proximal end. The increase in stiffness can be substantially smooth.

In a further embodiment, the tip member can be formed of the same material as the body of the elongate member. In another embodiment, the tip member can be formed of a different material to that of the body of the elongate member.

The tip member can be formed separately to the body of the elongate member and mounted thereto. For example, the tip member can be adhered to the first end of the body of the elongate member with a clear adhesive. In another embodiment, the tip member can be integrally formed with the body of the elongate member. The tip member can be formed from a silicone material.

In the above aspects, the elongate member is preferably preformed from a plastics material with memory and is preformed to the second configuration. The elongate member preferably has a first end that is firstly inserted into the implantee. In a preferred embodiment, the first configuration is preferably substantially straight. More preferably, the first configuration is straight. In a

preferred embodiment of these aspects, the elongate member preferably adopts a spiral configuration when in the second configuration.

In a preferred embodiment, the elongate member is formed from a suitable biocompatible material. In one embodiment, the material can be a silicone, such as a flexible silicone elastomer Silastic. Silastic MDX 4-4210 is an example of one suitable silicone for use in the formation of the elongate member. In another embodiment, the elongate member can be formed from a polyurethane or other similar materials.

In another embodiment, the stiffening element can comprise a monolithic optic fibre stylet. In another embodiment, the stiffening element can comprise a stylet formed of a plurality of optic fibres.

In a further aspect, the present invention is a stiffening element for an implantable tissue-stimulating device characterised in that the stiffening element comprises one or more optic fibres.

In this aspect, the tissue-stimulating device is preferably a cochlear implant electrode assembly device.

In this aspect, the stiffening element can comprise a monolithic optic fibre stylet. In another embodiment of this aspect, the stiffening element can comprise a stylet formed of a plurality of optic fibres.

The stylet can extend through a single lumen in the elongate member. In one embodiment, the lumen for the stylet can be cylindrical and also can have an opening formed therein. The stylet can extend out of the opening allowing the stylet to be manipulated and removed from the lumen during or following insertion of the device.

In one embodiment of the above aspects, a distal end of the stylet can be connected to an optical fibre termination means. The termination means preferably receives the proximal end of the stylet and can have a light source, eyepiece, and/or a camera lens mounted thereto. The termination means preferably receives light output by the light source and directs this light through

the one or more optic fibres to their distal ends. This light is then preferably able to pass through the transparent tip member of the carrier and illuminate at least the region of the cochlea adjacent the tip member.

The eyepiece and/or the camera lens preferably receive light reflected through the one or more optic fibres from an object illuminated by the light emitting from the distal end of the optical fibres. A magnifying means and/or focussing means can be incorporated, if necessary, into the termination means.

The camera lens is preferably part of a video camera that allows recordal of the image detected by the camera lens. The video footage is preferably used in real time during insertion of the array into a recipient's cochlea but can also be used as a means of reviewing the surgical procedure following completion of the surgery.

Preferably, while the first stiffening element is in position within the device, the carrier member will retain the first configuration, which as discussed previously, is preferably straight. If the first stiffening element is removed, the elongate member is free to adopt the curved, preferably spiral, second configuration desired of an implant after insertion into the cochlea.

The present invention provides a surgeon with a means to illuminate and visualise the region of the cochlear at least adjacent the distal tip of the elongate member as it is inserted into the cochlear. This provides the surgeon with a means to illuminate and visualise unexpected bone or tissue growth that might cause deflection of the member during its insertion and hence potential trauma to the wall of the duct of the cochlea receiving the member. The use of a stylet also provides the surgeon with a means to at least partially control the rate of curvature formation in a cochlear electrode assembly during insertion into the cochlea. Such increased control is envisaged to reduce the potential for trauma to the cochlea caused by electrode assembly insertion.

In a further aspect, the present invention comprises a method of implanting a tissue-stimulating device or cochlear electrode assembly device as defined herein in a body of an implantee.

In this aspect, the method can comprise a step of accessing the implantation site and then a step of inserting the device. During the insertion, the surgeon is able to use the optic fibre stylet to illuminate and visualise the region of the cochlea adjacent the tip of the member. Prior to insertion, the device is preferably substantially straight or straight. Following insertion, the device can adopt a second, preferably spirally curved, configuration.

Once implanted, the electrodes of the array can receive stimulation signals from a stimulator means. The stimulator means is preferably electrically connected to the elongate member by way of an electrical lead. The lead can include the one or more wires extending from each electrode of the array mounted on the elongate member.

In one embodiment, the lead can extend from the elongate member to the stimulator means or at least the housing thereof. In one embodiment, the lead is continuous with no electrical connectors, at least external the housing of the stimulator means, required to connect the wires extending from the electrodes to the stimulator means. One advantage of this arrangement is that there is no requirement for the surgeon implanting the device to make the necessary electrical connection between the wires extending from the electrodes and the stimulator means.

The stimulator means is preferably positioned within a housing that is implantable within the implantee. The housing for the stimulator means is preferably implantable within the bony well in the bone behind the ear posterior to the mastoid.

When implantable, the housing preferably contains, in addition to the stimulator means, a receiver means. The receiver means is preferably adapted to receive signals from a controller means. The controller means is, in use, preferably mounted external to the body of the implantee such that the signals are transmitted transcutaneously through the implantee.

Signals can preferably travel from the controller means to the receiver means and vice versa. The receiver means can include a receiver coil adapted to receive radio frequency (RF) signals from a corresponding transmitter coil

worn externally of the body. The radio frequency signals can comprise frequency modulated (FM) signals. While described as a receiver coil, the receiver coil can preferably transmit signals to the transmitter coil which receives the signals.

The transmitter coil is preferably held in position adjacent the implanted location of the receiver coil by way of respective attractive magnets mounted centrally in, or at some other position relative to, the coils.

The external controller can comprise a speech processor adapted to receive signals output by a microphone. During use, the microphone is preferably worn on the pinna of the implantee, however, other suitable locations can be envisaged, such as a lapel of the implantee's clothing. The speech processor encodes the sound detected by the microphone into a sequence of electrical stimuli following given algorithms, such as algorithms already developed for cochlear implant systems. The encoded sequence is transferred to the implanted stimulator/receiver means using the transmitter and receiver coils. The implanted stimulator/receiver means demodulates the FM signals and allocates the electrical pulses to the appropriate attached electrode by an algorithm which is consistent with the chosen speech coding strategy.

The external controller further comprises a power supply. The power supply can comprise one or more rechargeable batteries. The transmitter and receiver coils are used to provide power via transcutaneous induction to the implanted stimulator/receiver means and the electrode array.

While the implant system can rely on external componentry, in another embodiment, the controller means, including the microphone, speech processor and power supply can also be implantable. In this embodiment, the controller means can be contained within a hermetically sealed housing or the housing used for the stimulator means.

Brief Description of the Drawings

By way of example only, preferred embodiments of the invention are now described with reference to the accompanying drawings, in which:

Fig. 1 is a simplified cross-sectional view of one embodiment of an electrode assembly according to the present invention depicted in its first configuration;

Fig. 2 is a simplified side elevational view of the electrode assembly of Fig. 1 depicted with the stylet partially withdrawn;

Fig. 3 is a simplified side elevational view of the electrode assembly depicted implanted in the cochlea; and

Fig. 4 is a simplified schematic view of a light source, eyepiece, and camera for use with the optic fibre stylet of the present invention.

Preferred Mode of Carrying out the Invention

One embodiment of a cochlear implant electrode assembly according to the present invention is depicted generally as 10 in the drawings.

The depicted electrode assembly 10 has an electrical lead extending back to a receiver/stimulator housing. In considering this invention, it is to be understood that each electrode may have one or more wires (not depicted) electrically connected thereto and extending from each respective electrode back through the lead to the receiver/stimulator.

The assembly 10 comprises an elongate electrode carrier member 11 having a plurality of electrodes 12 mounted thereon. For the purposes of clarity, the electrodes 12 depicted in Fig. 1 are not necessarily shown to scale. The electrodes 12 are not depicted in Figs. 2 and 3 for reasons of clarity.

The depicted elongate member 11 is preformed from a resiliently flexible silicone with memory and is preformed to a curved configuration suitable for insertion in the scala tympani of the cochlea. The elongate member 11 has a first end 13 that is firstly inserted into the implantee on insertion of the assembly 10.

The elongate member 11 has a partly hemispherical tip member 29 integrally formed with its first end 13. The depicted tip 29 is formed from a transparent silicone and has a resilient flexibility substantially equal to that of the material used for the carrier member 11. The depicted tip member is transparent and acts as a lens so that light delivered to the first end 13 of the carrier member can illuminate at least the region of the duct of the cochlea adjacent the first end 13 when the member 11 is in the duct.

Disposed within a substantially cylindrical lumen 14 is a substantially straight optic fibre stylet 15. The stylet 15 is relatively stiffer than the elongate carrier 11 and has a stiffness that is sufficient to retain the silicone elongate member 11 in the straight configuration depicted in Fig. 1 during the insertion procedure of the member 11 in the cochlea of the recipient.

The stylet 15 extends through opening 17 in lumen 14 to a termination apparatus 40 depicted schematically in Fig. 4. The apparatus 40 receives the proximal end of the stylet 15. It comprises a light source 41, eyepiece 42, and a video camera 43. Light from the light source 41 is reflected within the apparatus 40 and transmitted through the stylet 15 to its distal end where the light can then exit the elongate member 11 through transparent tip 29 and illuminate the region of the cochlea adjacent the tip 29.

The eyepiece 42 and video camera 43 receive light reflected from objects illuminated by the tip of the distal end of the stylet 15 and allow examination thereof. While the termination apparatus 40 is depicted as having both an eyepiece 42 and camera 43, one of these devices could be omitted if desired.

While the elongate member 11 is manufactured with a preformed curved configuration, the assembly 10 is typically delivered to a surgeon with the stylet 15 in place. The placement of the stylet 15 in the lumen 14 is sufficient to hold the elongate member 11 in the straight configuration depicted in Fig. 1.

On insertion of the device 10 into the scala tympani of the cochlea 30, the surgeon can visualise the duct of the cochlea through the eyepiece 42 or output of the camera 43, with the duct being illuminated by light transmitted into

the cochlea via the stylet 15 and transparent tip member 29. This illumination and visualisation allows the surgeon to note and, if possible, avoid obstructions in the duct during the insertion process. When the first end 13 reaches the back of the basal turn, the surgeon can commence withdrawal of the stylet 15 from the lumen 14. This can be achieved by gripping and withdrawing the stylet 15 or by moving the termination apparatus 40, with the stylet 15 connected thereto, relatively away from the recipient's cochlea. As the stylet 15 is withdrawn, the elongate member 11 commences to re-curl (see Fig. 2).

As the elongate member 11 curls, the surgeon can continue to further insert the curled assembly 10 into the scala tympani duct until the desired insertion is attained. Upon desired insertion, the stylet 15 can be fully withdrawn through the opening 17 of the lumen 14. On full withdrawal of the stylet 15, the elongate member 11 is free to adopt the spiral configuration depicted in Fig. 3 with the electrodes 12 facing the modiolus within the cochlea 30 so that they are positioned as close as possible to the spiral ganglia thereof.

The stylet 15 provides the surgeon with greater control of the implantation procedure for the cochlear implant electrode assembly 10. The provision of greater control minimises the potential for trauma to the sensitive tissues inside the cochlea and also enhances the likelihood of successful placement of the assembly 10 at the first attempt.

While the preferred embodiment of the invention has been described in conjunction with a cochlear implant, it is to be understood that the present invention has wider application to other implantable electrodes, such as electrodes used with pacemakers.

It will be appreciated by persons skilled in the art that numerous variations and/or modifications may be made to the invention as shown in the specific embodiments without departing from the spirit or scope of the invention as broadly described. The present embodiments are, therefore, to be considered in all respects as illustrative and not restrictive.

Dated this twenty eighth day of June 2002

Cochlear Limited
Patent Attorneys for the Applicant:

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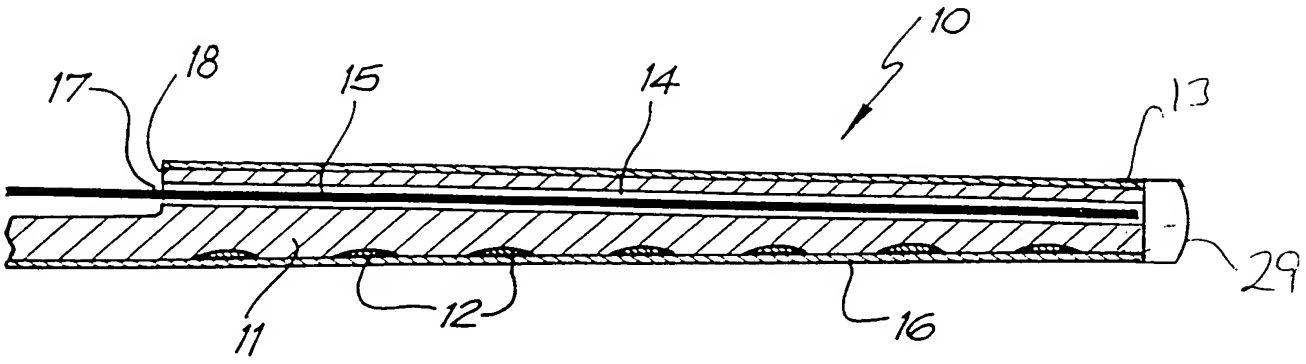


FIG. 1

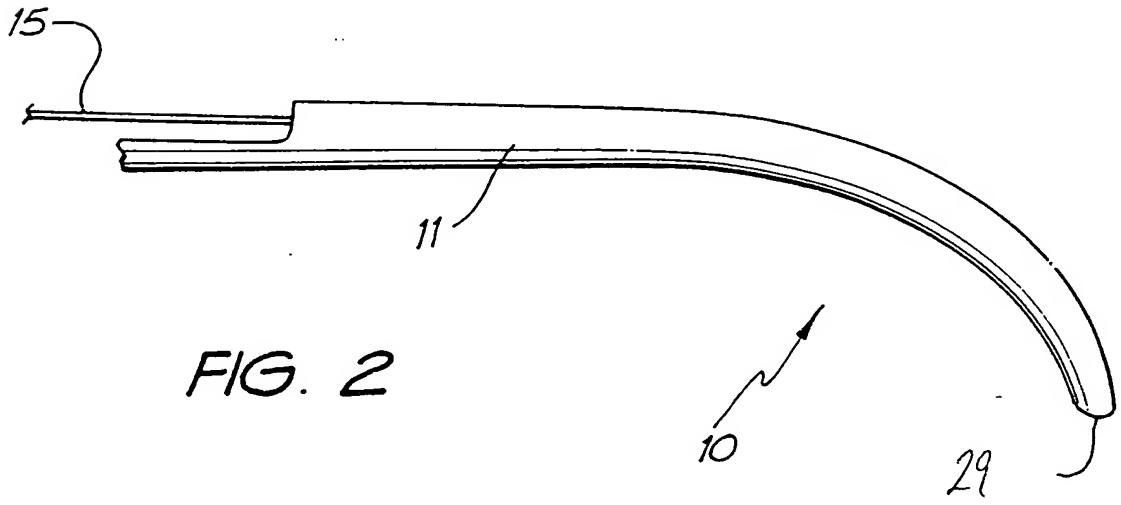


FIG. 2

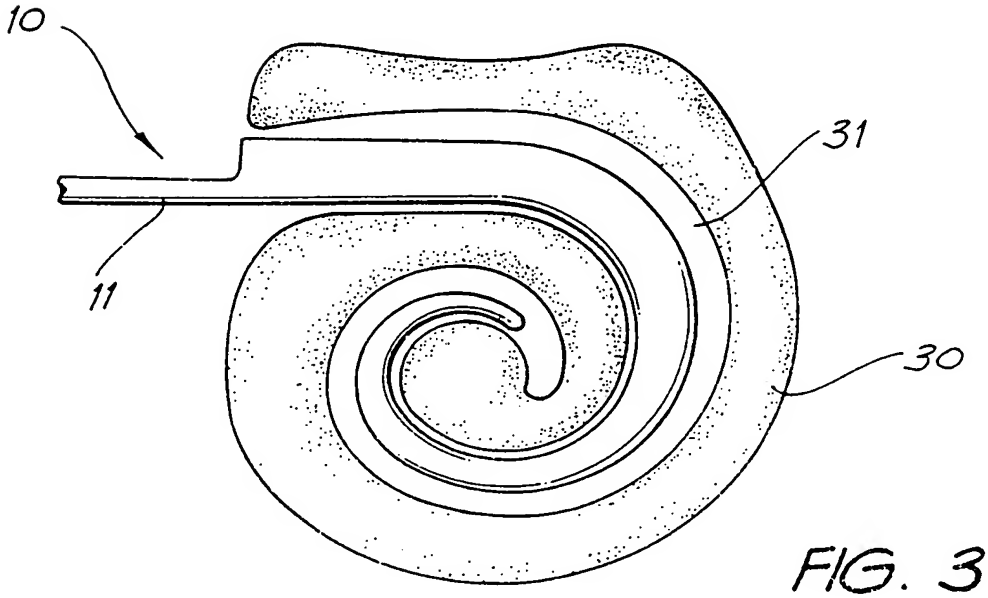
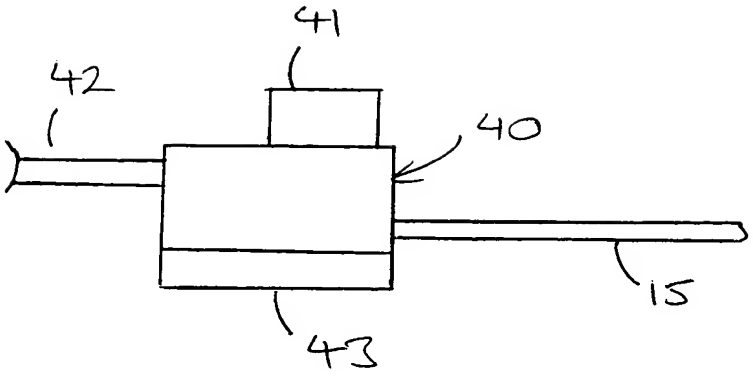


FIG. 3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